Pharmaceuticals, PCPs and other Compounds of Potential Concern

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EPA Region 3
Volunteer Monitoring Conference

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Terms and Definitions

- **PPCP** – Pharmaceuticals and Personal Care Products (name coined by Dr. Christian Daughton, EPA in 1999)

  Human drugs – prescription and OTC drugs
  Veterinary drugs
  Pet products and supplements
  Food Supplements – caffeine, nicotine
  Fragrances
  Sun-screen agents
  Lotions, shampoos, soaps, deodorants, toothpaste
  Cosmetics

- **CPC** – Compounds of Potential Concern

  Fire retardants – PBDEs, or polybrominated diphenyl ethers (penta, octa, and deca)
  Compounds – bisphenol A, phthalates

http://www.epa.gov/nerlesd1/chemistry/ppcp/images/seatac.pdf

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"PC" Acronyms

New term in consideration as of July, 2007:

MICRO-CONSTITUENTS

PCP — **Personal Care Products**

PC — **Pollutants of Concern**

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Terms and Definitions

Pharmaceutical waste

- Controlled substances
  - Schedule I - Illegal drugs
  - Schedule II – V - High to low potential for abuse
- Non-Controlled substances
  - Prescription drugs
  - OTC (over the counter) drug that is unwanted, unused, or expired

Terms and Definitions

EDCs – Endocrine Disrupting Compounds

An endocrine disruptor is a synthetic chemical that either mimics or blocks hormones and disrupts the body's normal functions when absorbed into the body.

Most common EDCs in wastewater treatment are:

- reproductive steroid hormones (especially estrogens), which showed up in 40% of the surveyed US water, and
- estrogenic biodegradation products of alkylphenol ethoxylate surfactants (shampoos and soaps) which showed up in 70% of the surveyed US waters (according to the USGS study

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Terms and Definitions

- "Emerging" pollutants are pollutants that we have become aware of for various reasons.

  Some are "new" - just created/formulated.

  Some are a new combination form of previously known pollutants.

  Some just got noticed as effects are seen, analytical methods improve and detection limits are lowered.

PPCPs have existed in the environment for as long as they have been used commercially.

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Where can you find PPCPs?

ALL municipal sewage, regardless of location, will contain PPCPs. Issue is not unique to any particular municipal area.

Each geographic area will differ only with respect to the types, quantities, and relative abundances of individual PPCPs.

PPCPs can be incurred by air deposits as well as by water.

PPCPs are being found in all tested waterways, and are in drinking water and bottled water

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PPCPs are showing up everywhere

The most notable state-side study was conducted by the U.S. Geological Survey (USGS) in 1999-2000, where 139 rivers in 30 states were tested and found that 80 percent (111 rivers) of them contained 31 different drugs.

U.S. studies have also confirmed the presence of PPCPs, such as naproxen, estrone, and clofibric acid in drinking water. ..."it is no longer a question of if these compounds are in our waters -- they are."

Canada found cholesterol reducing drugs in the drinking water of 4 cities

Germany found 31 different PPCPs in 40 German rivers and streams

England found prozac in trace amounts in groundwater

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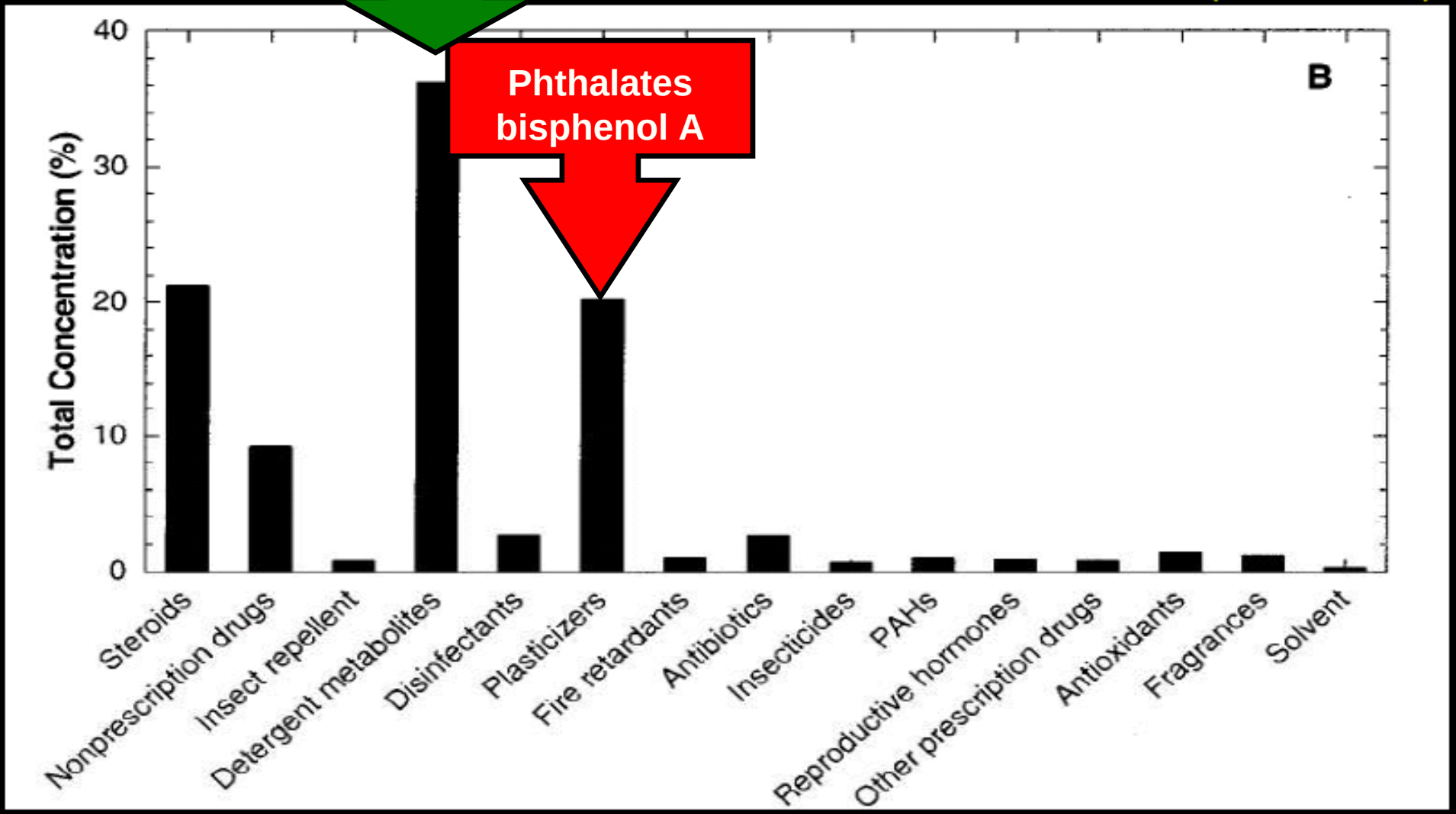
Phar ones, and Organic Waste Conta lants in U.S. Streams (USGS)

SURFACTANTS
nonylphenol ethoxylates, or NPEs
alkylphenol ethoxylates, or APEs

Phthalates
bisphenol A



Kolpin et al., Environ Sci Technol (2002)

Problems caused by PPCPs

- “Gender-bending” in fish – the testes of male fish have female eggs (Mississippi R., Potomac R., Colorado R., St. Lawrence R.)
- Low sperm counts in young males living in US (phthalates being looked at)
- Male birds with female organs (Great Lakes)
- Feminized male alligators (Florida)
- Testosterone levels in men in age specific groups is declining over past 20 yrs (study in Boston)
- 1200 male babies are born with genital abnormalities every year in the UK – correlation to higher phthalate conc. in mothers’ milk.
- Lobsters are having developmental issues, as well as problems with shell growth and reproduction (Maine)

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Effluent changes gender of fish

By BOONSRI DICKINSON and TODD NEFF
Scripps Howard News Service Tuesday, December 12, 2006

Boulder Creek, CO

50:50 female:male ratio of white suckers upstream of POTW

90:10 downstream

Fish are affected by conc. as low as 1.0 ppt of 17 beta estradiol (human estrogen)

Experiment showed fish feminized in 7 days of exposure

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Intersex sunfish found for first time in Potomac basin

By DAVID DISHNEAU – AP January 23 2007

- SHEPHERDSTOWN, W.Va. -- Scientists studying intersex fish in the Potomac River basin have found the abnormality for the first time in redbreast sunfish, the third species affected by the mysterious phenomenon, a federal fish pathologist said Tuesday.

- Intersex fish possess both male and female characteristics. For example, some male fish have been found with immature eggs in their testes.

- The phenomenon was previously documented in smallmouth and largemouth bass in the Potomac River and some of its tributaries in Maryland, Pennsylvania, Virginia and West Virginia.

- Dr. Vicki Blazer (USGS) said intersex and fish kills may be related because many of the killed fish appear to have had suppressed immune systems. There is increasing evidence that immune cells and disease resistance are affected by contaminants including chemical compounds that stimulate estrogen production, Blazer said.

- http://www.dailypress.com/news/local/virginia/dp-wv--intersexfish0118jan18,0,7278225.story?coll=dp-headlines-virginia

Our “canary in the mine”...

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Why didn't we notice these PPCPs before?

- The scope of "testing for everything" is variable, and always increasing.
- What one finds usually depends on what one looks for.
- Testing is expensive. We tend to narrow the options by looking for 'familiar' things that have the potential to cause the problem seen. When those things aren't present, we expand the search.
- Only those compounds targeted for monitoring have the potential for being identified and quantified. Those compounds not targeted will elude detection.

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Male to Female Ratios

Study in the US on white male births

1970	105.5 males: 100 females
2001	104.6 males: 100 females

There was a greater decline in males in Japan for the same time period.

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Shift in Gender Balance

- Increase in male fetal deaths
- Reduced testosterone levels and reduced sperm count
- Testicular cancer has increased by 50 percent and is affecting ever-younger men
- One in every four to five couples nowadays reports difficulty with reproduction

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Shift in Gender Balance

- There also is mounting evidence that exposure to contaminants at home, on the job, along with other workplace issues, can affect the DNA of sperm, increasing the tendency of men to father children with birth defects.

- New Delhi, Apr 25, 2007: Impotency among Indians is rising with one in every six persons becoming sterile due to various environmental and lifestyle changes and genetic factors, according to research conducted by the Indian Council of Medical Research (ICMR).

  - Increased use of pesticides
  - Increased use of birth control pills
  - Tight fitting clothing

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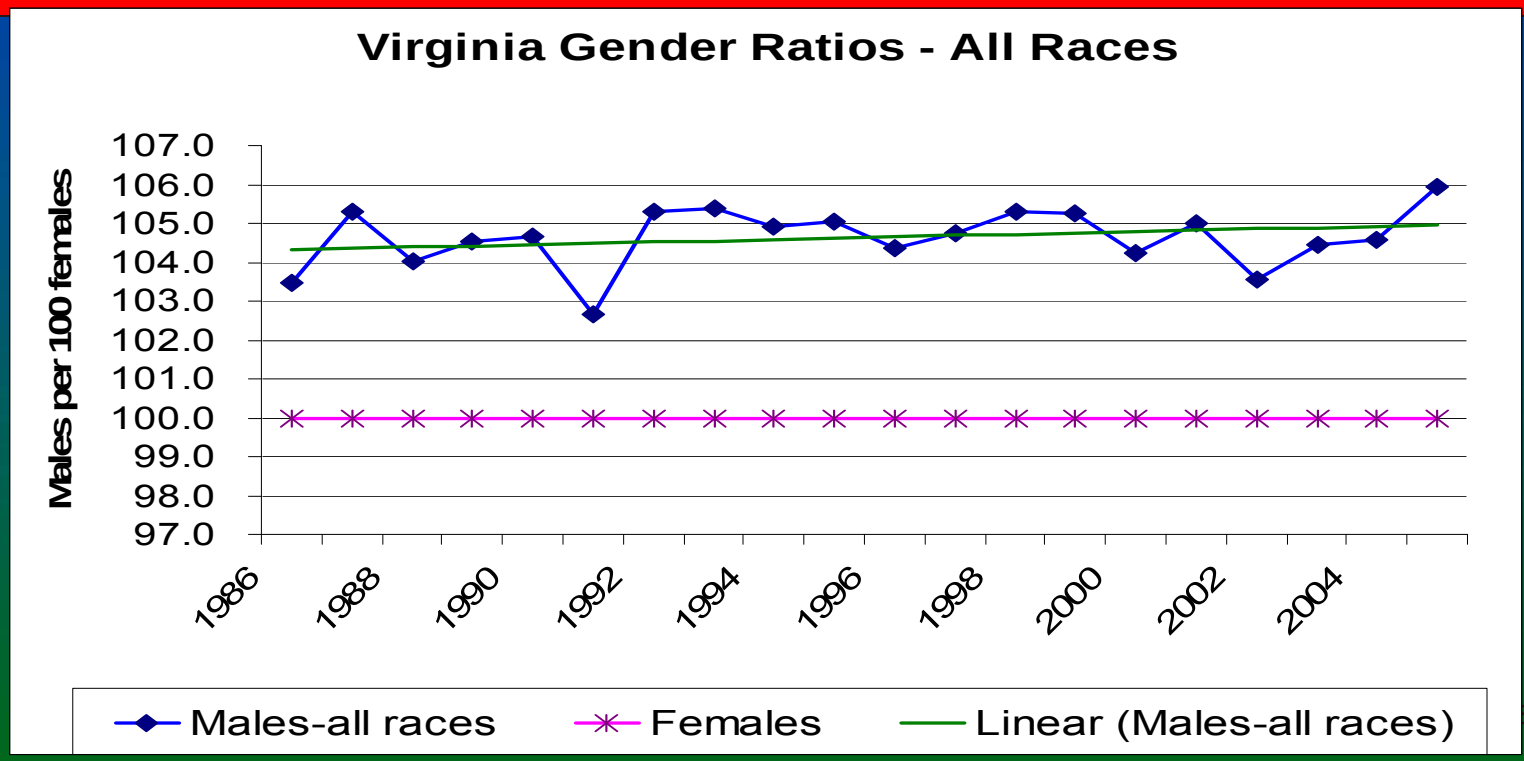
Statistics in Virginia on Gender Ratios

All Races

1986 103.5 males: 100 females

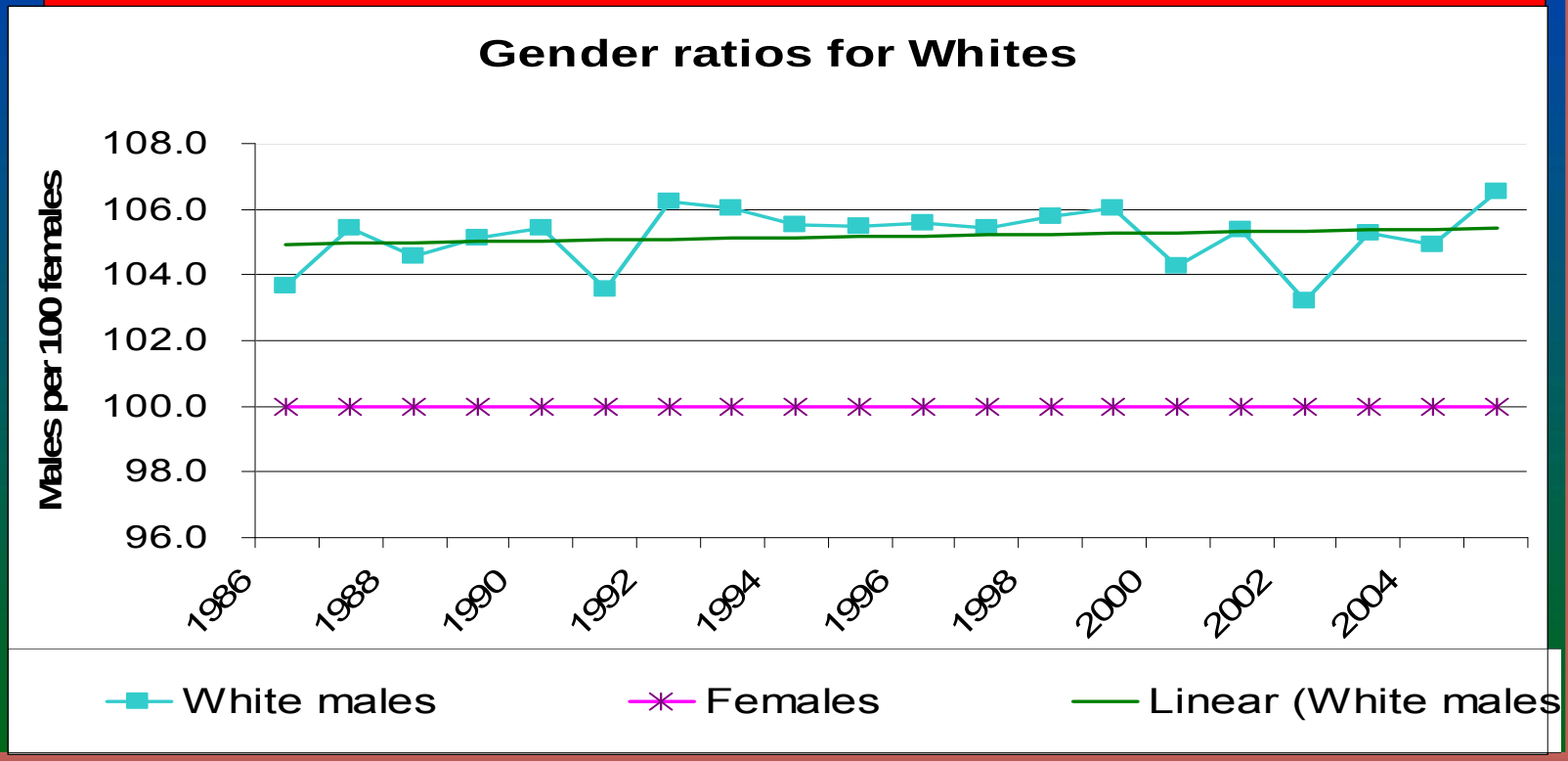
2005 105.9 males: 100 females



Statistics in Virginia on Gender Ratios

Whites

1986	103.6 males: 100 females
2005	106.5 males: 100 females

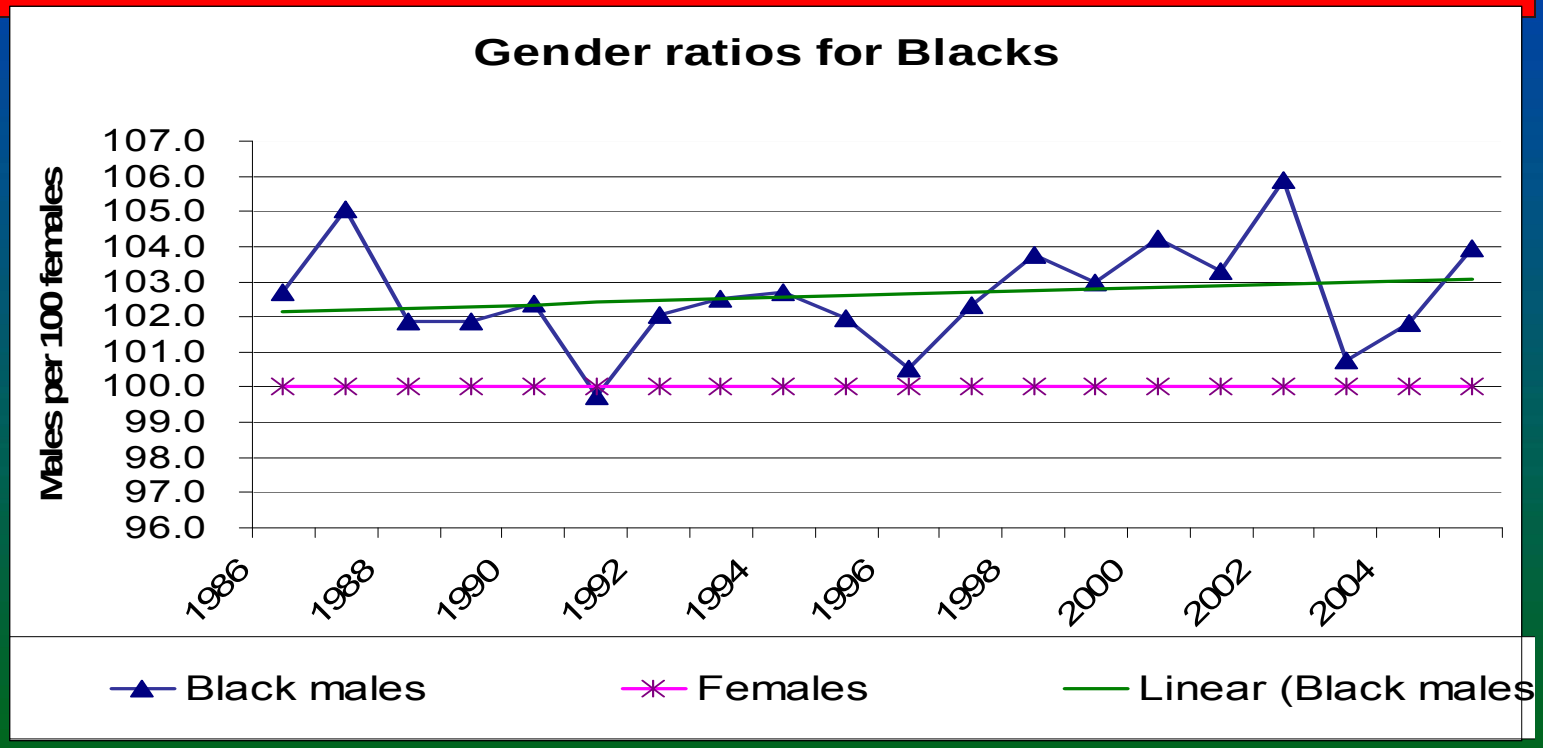


Statistics in Virginia on Gender Ratios

Blacks

1986 102.7 males: 100 females

2005 103.9 males: 100 females

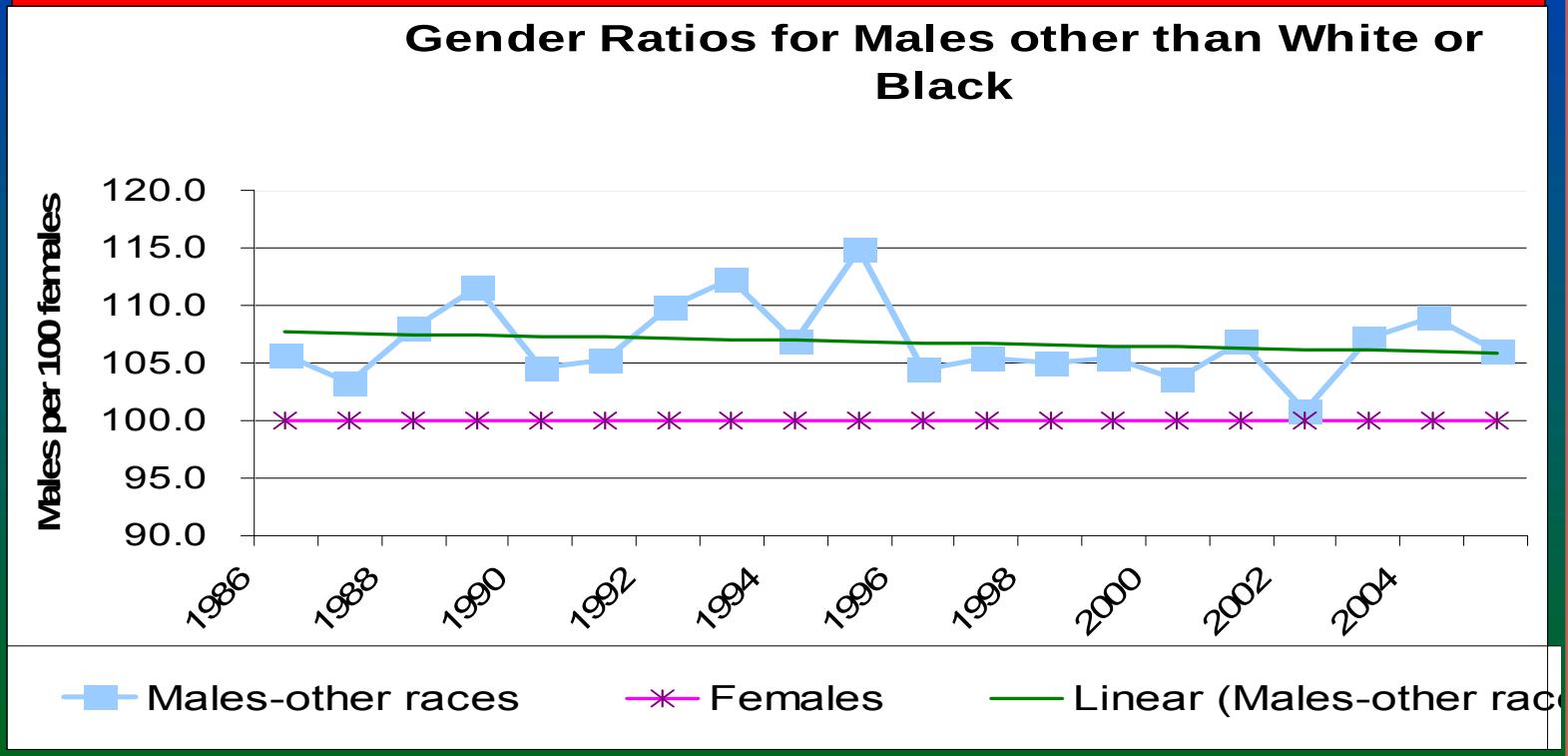


Statistics in Virginia on Gender Ratios

Non-white, Non-Black

1986 105.7 males: 100 females

2005 106 males: 100 females



Concerns with PPCPs

- Exposure to non-target organisms could be significant.
- Even though PPCPs may degrade in a short time period, constant input via treated sewage and run off makes them appear persistent for chronic toxicity to aquatic organisms.
- Potential exists for subtle effects (e.g., neurobehavioral change), even at ppb levels (µg/L).
- Some effects may not be apparent for weeks, months, or years after initial exposure (delayed onset toxicity).
- There are many challenges in dealing with unknown toxicants, in unknown amounts, in varied conditions either singly or in combination with other potential toxicants
- Potential for additive (cumulative) and interactive (synergistic) effects from the multiple exposures.

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How do PPCPs get in the waters?

- Purposeful discharge:

  Disposal of expired or unwanted PPCPs to toilets and drains as well as trash.

- Inadvertent discharge:

  Excretion to sewage from humans ("pass-through"), pets, and agricultural sources (e.g., CAFOs – concentrated animal feeding operations)

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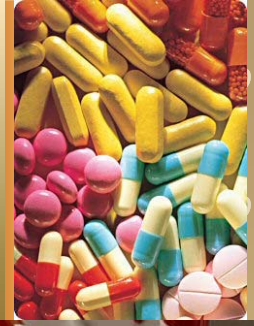

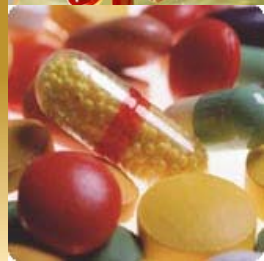

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Inadvertant PPCP Sources

- POTWs, Septic tanks
- Leaching from landfills
- Runoff from CAFOs and excretions from medicated pets (up to 90% of ingested antibiotics pass through animals and humans)
- Aquaculture antibiotics
- Direct discharge of raw sewage (e.g. overflow, straight-piping)
- Runoff and products from genetically altered crops
- Outside washing of people/animals to dislodge externally applied meds and PCPs
- Naturally occurring sources of estrogen-like compounds in wines, soy products, decaying vegetation
- Discharge of sewage from boats
- Pesticides
- Flame retardants distributed by air as dust

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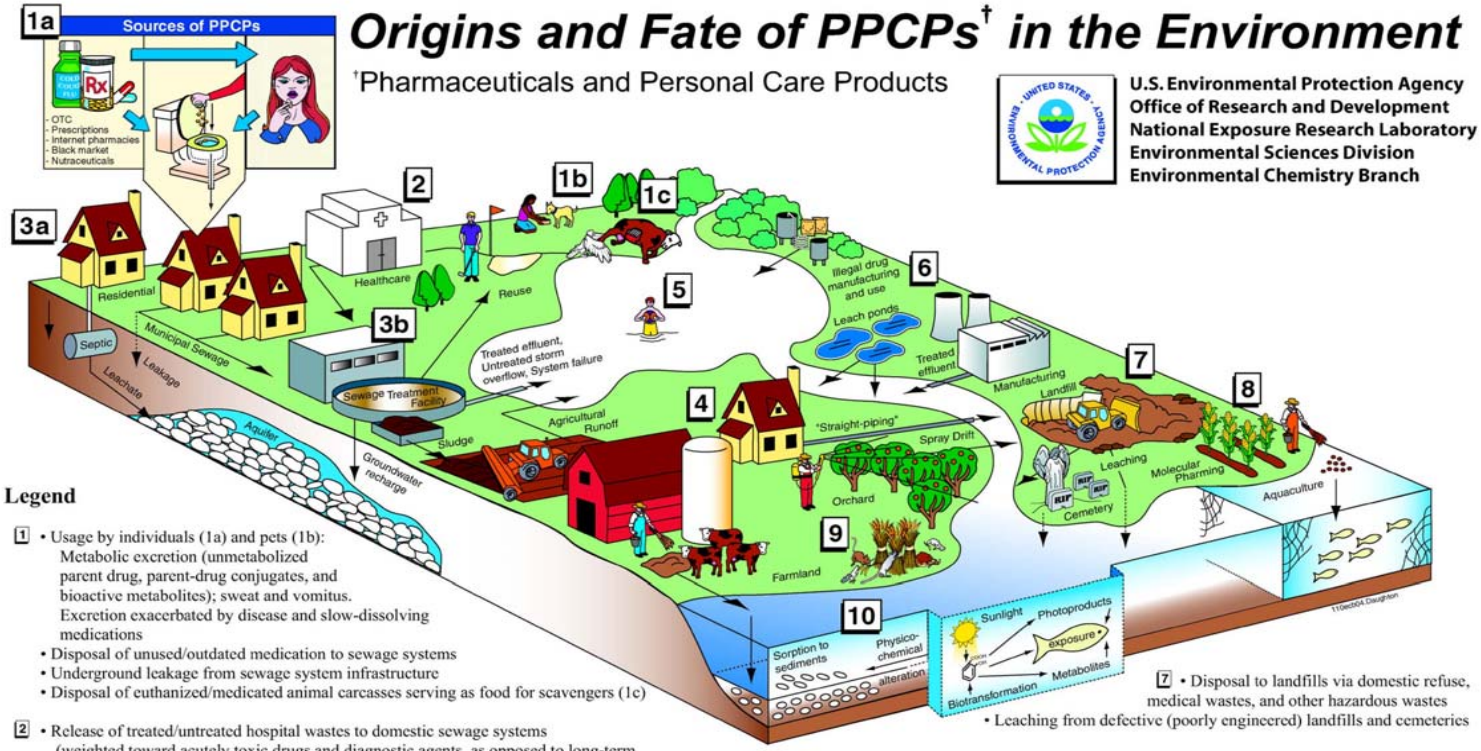
Origins and Fate of PPCPs† in the Environment

†Pharmaceuticals and Personal Care Products

U.S. Environmental Protection Agency
Office of Research and Development
National Exposure Research Laboratory
Environmental Sciences Division
Environmental Chemistry Branch



Legend

1 • Usage by individuals (1a) and pets (1b):
Metabolic excretion (unmetabolized parent drug, parent-drug conjugates, and bioactive metabolites); sweat and vomitus. Excretion exacerbated by disease and slow-dissolving medications
• Disposal of unused/outdated medication to sewage systems
• Underground leakage from sewage system infrastructure
• Disposal of euthanized/medicated animal carcasses serving as food for scavengers (1c)

2 • Release of treated/untreated hospital wastes to domestic sewage systems (weighted toward acutely toxic drugs and diagnostic agents, as opposed to long-term medications); also disposal by pharmacies, physicians, humanitarian drug surplus

3 • Release to private septic/leach fields
• Treated effluent from domestic sewage treatment plants discharged to surface waters or re-injected into aquifers (recharge)
• Overflow of untreated sewage from storm events and system failures directly to surface waters

4 • Transfer of sewage solids ("biosolids") to land (e.g., soil amendment/fertilization)
• "Straight-piping" from homes (untreated sewage discharged directly to surface waters)
• Release from agriculture: spray drift from tree crops (e.g., antibiotics)
• Dung from medicated domestic animals (e.g., feed) - CAFOs (confined animal feeding operations)

5 • Direct release to open waters via washing/bathing/swimming

6 • Discharge of regulated/controlled industrial manufacturing waste streams
• Disposal/release from clandestine drug labs and illicit drug usage

7 • Disposal to landfills via domestic refuse, medical wastes, and other hazardous wastes
• Leaching from defective (poorly engineered) landfills and cemeteries

8 • Release to open waters from aquaculture (medicated feed and resulting excreta)
• Future potential for release from molecular pharming (production of therapeutics in crops)

9 • Release of drugs that serve double duty as pest control agents:
examples: 4-aminopyridine, experimental multiple sclerosis drug → used as avicide; warfarin, anticoagulant → rat poison; azacholesterol, antilipidemics → avian/rodent reproductive inhibitors; certain antibiotics → used for orchard pathogens; acetaminophen, analgesic → brown tree snake control; caffeine, stimulant → *coqui* frog control

10 Ultimate environmental transport/fate:
• most PPCPs eventually transported from terrestrial domain to aqueous domain
• phototransformation (both direct and indirect reactions via UV light)
• physicochemical alteration, degradation, and ultimate mineralization
• volatilization (mainly certain anesthetics, fragrances)
• some uptake by plants
• respirable particulates containing sorbed drugs (e.g., medicated-feed dusts)

Christian G. Daughton, U.S. EPA-Las Vegas

January 2004
(original February 2001)

http://epa.gov/nerlesd1/chemistry/pharma/images/drawing.pdf
from: http://epa.gov/nerlesd1/chemistry/pharma/

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Drink caffeine, control frogs!

Why can't the treatment plants get the PPCPs out?

- POTWs are not primarily designed to remove PPCPs
- Technologies that are promising* are:
  - Oxidation
  - Ozonation
  - Activated carbon
  - Reverse osmosis
- POTWs with nutrient removal are removing the majority of PPCPs due to the longer solids retention times (Science News – December 27, 2006 http://pubs.acs.org/subscribe/journals/esthag-/2006/dec/science/kc_remove_ppcp.html)
- Technology must not create pollutant by-products that are toxic

* From the Poseidon Report, pub May 2006

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How many chemicals are there?

- As of August 2005, over 26 million organic and inorganic substances had been documented

(indexed by the American Chemical Society's Chemical Abstracts Service in their CAS Registry; excluding bio-sequences such as proteins and nucleotides)

- Less than 1% were inventoried or regulated by numerous government bodies worldwide

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Known Chemicals of Particular Concern with Regard to Human Reproductive Health

Chemical Group	Common Uses	Reproductive Health Concerns
alkyl phenols and related chemicals	•industrial and institutional cleaning sector (including domestic cleaning) •textile and leather processing •personal care products •pesticide production	•hormone mimicking activities •reduced male fertility, testicular size, sperm quality
phthalates	•plasticizers in PVC and special polymer applications •gelling agents •solvents and fixatives in cosmetics and other personal care products (PCPs)*	•testicular toxicity •reduced anogenital distance, cleft phallus, hypospadias and undescended testes in immature males •reduced male and female fertility •fetal toxicity (possibly leading to death or malformations)
brominated flame retardants	•as flame retardants in industrial and electrical appliances, vehicles, lighting, wiring as well as textiles, furnishing and insulating materials such as polystyrene	•estrogen mimicking •birth defects in rodents documented •impacts on nervous system and behavioral development
organotin compounds	•PVC UV stabilizers •agrochemicals and biocides •antifoulants – TBT •catalysts	•inhibition of steroid hormone production •adverse impact on in-utero development of fetus including abnormalities in genital development in male fetuses
bisphenol-A and its derivatives	•production of polycarbonate plastic used in products like baby bottles, CDs, motorcycle windshields, etc. •production of epoxy resins used in things like food packaging	•estrogenic activity •altered male reproductive organs •early puberty induction •reduced breast feeding
artificial musks	•fragrance mixtures for detergents, fabric, conditioners, cleaning agents, air fresheners, and other household products •cosmetic products such as soaps, shampoos and perfumes	•estrogenic activity •anti-estrogenic activity

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Bisphenyl A

- identified by an industry triangle symbol and the number seven
- acts like a synthetic female sex hormone
- Derived from petroleum
- Chief ingredient in polycarbonate, the rigid, translucent hard plastic used in water bottles and many baby bottles.
- In resins that line most tin cans, dental sealants, car parts, microwaveable plastics, sports helmets and CDs.
- Extrapolating from the results of animal experiments, may be linked to the unexplained human health trends of something going haywire with sex hormones
  - early onset of puberty
  - declining sperm counts
  - huge increase in breast and prostate cancer
- Urine testing in the United States suggests that about 95 per cent of the population have been exposed

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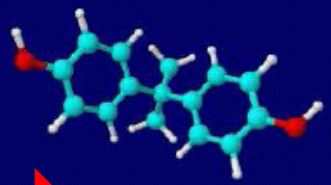
Beware of Study Bias in Articles

Bisphenol A : Many studies showing impact at low levels

Through Nov. 2006: 161 animal studies of BPA at current human exposure levels



	Effect	No effect
12 funded by industry	0	12
149 funded by gov't	138	11

Over 80 *in vitro* studies also show low dose effects.

Updated from Welshons *et al.* 2006

Environmental Health Sciences

http://www.mawaterquality.org/themes/policy/ed_workshop_docs/5_Myers_ED_and_Human_Health.pdf

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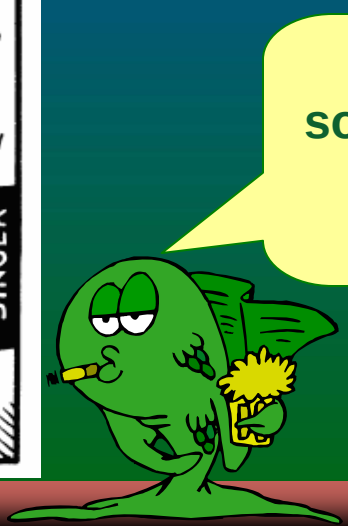
Whose problem is this?

WE

are the source,

We

have to be the solution.



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Used with permission from Andy Singer

How should home pharmaceuticals be disposed of?

Feb 20, 2007: EPA and Federal Government:

- Remove from pill bottle and put in container with lid or sealable baggie
- Mix in something to make meds "undesirable"
- Throw in trash
- Remove or cover identifying info on pill bottle before discarding

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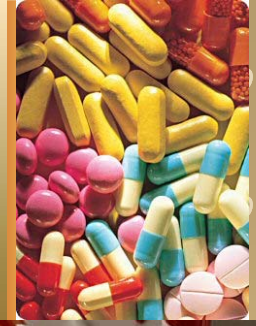
Another method for disposal of home pharmaceuticals

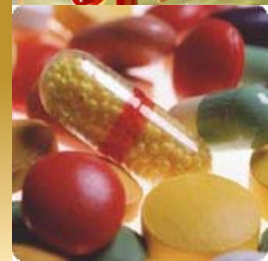
Remove or hide identifying info

Add something unpalatable

Tape shut

This method and pictures came from Florida EPA





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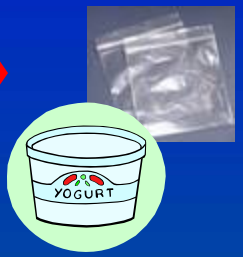
Environmental Improvement?

Before:

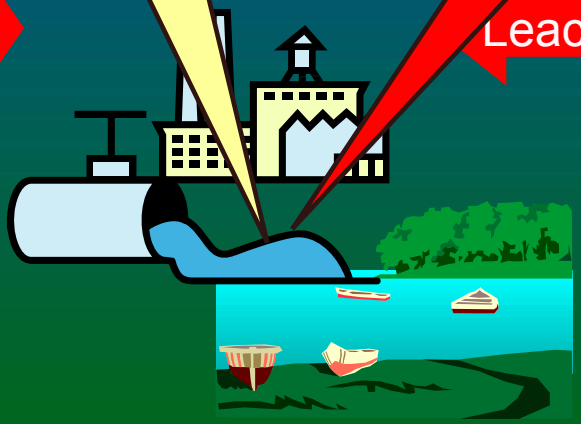
Now:

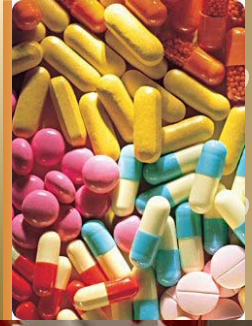


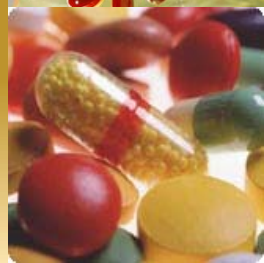
Days

Years

Leachate







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The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

Actiq (fentanyl citr
Daytrana Tran ch (methylpheni
Duragesic T l System (fentanyl)
OxyCont done)
Avinza es (m lfate)
Barac blets (ent
Reya sules (atazan
Tequ g
Zerit u
Mepe T
Percoc odone and Acetaminophe
Xyrem (S Oxybate)
Fentora (fe cal tablet)

We need to keep things OUT of the water!

BAD IDEA!!!

Note: Patients sh terial accompanying their medication for specific

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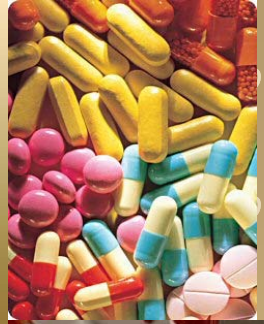




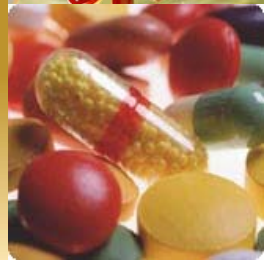

Why don't we have better options for the disposal of prescription and OTC Drugs?

This is mostly the result of DEA regulations that strictly control the transfer of drugs and controlled substances, along with RCRA regulations for transport and destruction. Virginia pharmacies cannot accept returns from patients.

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Drug collection programs require assistance of Police/Sheriff because of controlled substances

- Controlled Substances Act of 1972
  - 21 CFR § 1301.11(a), § 802(11), and § 841(a) prohibit the transfer of dispensed controlled substances from the patient to any other entity registered with the DEA to handle or manage controlled substances.
  - 21 CFR § 1301.24 Exempts law enforcement from the above
  - 5-15 % of collected items may be controlled substances

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Are we too drug dependant?

A group in Maine is looking at whether doctors prescribe more drugs than are necessary. Maine is #1 in prescription drug usage and related crime.

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Resource Conservation & Recovery Act (RCRA)

- Applies to non-controlled substances
- Regulates transport, treatment & disposal of hazardous waste
- Hazardous waste may constitute 10% of collected items
- Hazardous “P-listed” waste must be destroyed in a hazardous waste incinerator
- “Household” hazardous waste is exempt from RCRA, while “commercial” haz waste is not

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Pilot Programs for Drug Collection

- "One-time" drug collection event
  - Need staff, pharmacist and police
  - Sort and inventory for controlled/non-controlled
- Collection boxes located at police stations for controlled/non-controlled drugs – dispose as hazardous waste (CA)
- Collection boxes for non-controlled substances at pharmacies for convenience (WA)
- Adult care facilities defined as "residences" for drug collection to facilitate drug destruction (OR)

Federal agencies need to adjust their regulations to allow for pharmaceutical collection and disposal!

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How to reduce the effects of PPCPs

- Education of the public by DEQ and EPA to protect themselves and future generations
- Disposal habits of the public, health care industry and manufacturers need to improve (P2, H2E, etc.)
- Regulations that inhibit collection and disposal of pharmaceuticals need to change nationally

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How to reduce the effects of PPCPs

- Products
  - Manufacturers should consider more environmentally suitable alternatives in their products (reduce phthalates, fire retardants, mercury, etc.)
  - Product labeling must be improved to show product makeup
  - Consumers should select products that are safer to dispose of

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Adapting to Pollution?

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Policy and Legislation

Washington

The bill would ban three forms of polybrominated
diphenyl ethers, or PBDEs, commonly referred to as
p
conditions are met.

California

The California Safe Cosmetics Act, which took effect on Jan. 1, 2007 requires cosmetics companies to tell state health authorities if a product contains any chemical on several government lists covering possible cancer-causing agents or substances that may harm the reproductive system.

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Future topics where PPCPs could play major roles

- Water recycling: With water reuse, especially "toilet-to-tap" programs, the occurrence of even ultra-trace levels of human-use drugs in water serves to highlight to the public what the origin of the water was. This risk-communication/perception problem will pose major problems with regard to public acceptance.
- Biosolids: The occurrence and fate of PPCPs in biosolids was unknown (NRC July 2002 report: *Biosolids Applied to Land: Advancing Standards and Practices*).
- Biopharming: Environmental ramifications of molecular farming or "biopharming" (plant-made pharmaceuticals) are unknown.
- Nanomaterials: The environmental fate and ramifications of nanomaterials (which will play ever-growing roles in nanomedicine) are unknown.
- Homeland Security: Certain PPCPs hold the potential for being used in water sabotage (e.g., psychoactive agents; teratogens).

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Sources of Information on PPCPs

- Site to check for news articles on the subject worldwide
  http://www.environmentalhealthnews.org/topic.jsp?term=Topic%2Fedcs&title=EDCs
- The New England Interstate Water Pollution Control Commission is putting on a conference on PPCPs in Maine for August 07
  http://www.neiwpcc.org/Index.htm?ppcpconference/index.htm~mainFrame
- Pharmacy waste list server
  http://lists.dep.state.fl.us/cgi-bin/mailman/listinfo/pharmwaste
- USGS Emerging Contaminant Project site
  http://toxics.usgs.gov/regional/emc/
- The Poseiden Report – Study on effectiveness of waste water technologies on PPCPs in WW and DW – May 06
  http://poseidon.bafg.de/servlet/is/2884/

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More resources

- http://www.epa.gov/nerlesd1/chemistry/pharma
  This is EPAs site with references, explanations, etc. on the PPCP issue

- Daughton CG. "**Groundwater Recharge and Chemical Contaminants: Challenges in Communicating the Connections and Collisions of Two Disparate Worlds**," *Ground Water Monitoring & Remediation*, Spring **2004**, *24*(2):127-138 ; available at:
  http://www.epa.gov/nerlesd1/chemistry/ppcp/images/water-reuse.pdf

- This document (*Pharmaceuticals & Personal Care Products: Overviews of Environmental Issues*) can be accessed from the following page on the U.S. EPA's PPCPs web site:
  http://epa.gov/nerlesd1/chemistry/pharma/overview.htm

- Daughton C.G. "Groundwater Recharge and Chemical Contaminants: Challenges in Communicating the Connections and Collisions of Two Disparate Worlds," In Fate and Transport of Pharmaceuticals and Endocrine Disrupting Compounds (EDCs) During Ground Water Recharge (special issue), *Ground Water Monitoring & Remediation*, **2004**, 24(2): 127-138.
  http://www.epa.gov/nerlesd1/chemistry/ppcp/images/water-reuse.pdf

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Newscast on Mississippi River

http://www.kare11.com/video/player.aspx?aid=37038&bw

This is a good overview of the problem and sources.

This is a TV news clip from Jamaica Bay, NY

http://video.wnbc.com/player/?id=133971

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